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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/246,034	05/18/94	PLATZ	R ITSY00200US

GROMET, N EXAMINER

18N1/0909

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ART UNIT	PAPER NUMBER
1815	5

DATE MAILED: 09/09/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 6/30/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-10 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: At page 10, line 11, --solution-- should be inserted after "saline". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Platz et. al. (World Patent Application No. 91/16038).

Platz et. al. teaches that interferons may be aerosolized to a dry powder formation that contains human serum albumin and a carbohydrate as stabilizing/bulking agents, and has a particle size of between 0.5 to 10 microns (Platz, page 4, lines 15-28 through page 5, lines 1-2). Platz teaches that the particle size preferable for intrapulmonary administration is between 0.5-4 microns (Platz, page 7, lines 6-10). Platz teaches a specific dry powder composition that contains interferon-beta, human serum albumin, sodium chloride, and sorbitol (a carbohydrate

bulking/stabilizing material) (Platz, page 9, lines 24-29). Platz teaches that the particle size of this composition is less than 4 microns (Platz, page 11, Table 2). Inherently, since the composition contains only those ingredients listed above, there are no penetration enhancers present in the composition. Platz teaches that this composition may be administered with a dry-powder inhaler to administer therapeutically meaningful dosages of interferon (Platz, page 9, lines 1-17). Platz, by teaching the therapeutic use of a dry powder formulation of interferon via intrapulmonary administration, anticipates Applicants' claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

5. Claim 9 is rejected under 35 U.S.C. § 103 as being unpatentable over Platz et. al. (World Patent Application No. 91/16038) in view of Patton et. al. (World Patent Application No. 93/00951).

Platz et. al. teaches that interferons may be made into dry powder formulations for intrapulmonary administration via a dry powder inhaler as described above.

Platz does not teach that the dry powder interferon composition is aerosolized by the dispersement of a gas stream, nor that the aerosol is captured in a chamber with a mouthpiece.

Patton teaches an apparatus for the aerosolization of a dosage of a medicament for inhalation that comprises dispersion of a specific amount of the medicament in a volume of gas, wherein the medicament is in the form of a dry powder (Patton, page 4, lines 28-36). Patton also teaches that the aerosolized dosage flows into a chamber and through a mouthpiece to the patient (Patton, page 4, lines 37-38 through page 5, line 1). It would have been obvious to one with ordinary skill in the art at the time Applicants' invention was made to use Patton's

aerosolizer to aerosolize Platz's dry powder interferon formulation because this aerosolizer will effectively give a metered dose of interferon intrapulmonarily to any patient in an effective fashion, thereby enabling the patient to obtain needed treatment, resulting in better health.

6. Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Platz et. al. (World Patent Application No. 91/16038) in view of Radhakrishnan (U. S. Patent No. 5,049,389).

Platz et. al. teaches that interferons may be made into dry powder formulations for intrapulmonary administration via a dry powder inhaler as described above.

Platz does not teach that the interferons may be made into a dry powder formulation by the technique of spray drying.

Radhakrishnan teaches that interferon may be encapsulated in liposomes, which, in turn, may be subjected to powder formation by either spray drying or lyophilization for use in inhalation therapy wherein the particle size of the powder formulation is 2.1 microns or less (Radhakrishnan, col. 14, lines 22-45 and col. 20, lines 25-68 through col. 21, lines 1-5). It would have been obvious to one with ordinary skill in the art at the time Applicants' invention was made to use either the spray drying technique of Radhakrishnan or the lyophilization and milling technique of Platz to form a dry powder composition of interferon because these are functionally equivalent processes, yielding a

dry powder composition for intrapulmonary administration of interferon, and it is obvious to substitute one functional equivalent for another.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Nancy J. Gromet, whose telephone number is (703) 308-3673. The Examiner can normally be reached on Monday-Thursday from 8:00 AM-5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael G. Wityshyn, can be reached at (703) 308-4743. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)308-0196.

Jeffrey E. Russel

JEFFREY E. RUSSEL
PRIMARY PATENT EXAMINER
ART UNIT 1815

Nancy J. Gromet
August 19, 1994